



JuanB Perez/DC/USEPA/US
11/15/2006 04:42 PM

To NCIC HPV@EPA

cc

bcc

Subject Fw: HPV Update CAS 1709-70-2

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----- Forwarded by JuanB Perez/DC/USEPA/US on 11/15/2006 04:42 PM -----



Balcomb Richard PX US
<richard.balcomb@cibasc.com>

11/15/2006 03:53 PM

NCIC OPPT@EPA, Rtk Chem@EPA, Diane
Sheridan/DC/USEPA/US@EPA, Walter
To Cybulski/DC/USEPA/US@EPA, Charles
Auer/DC/USEPA/US@EPA, Jeffrey
Taylor/DC/USEPA/US@EPA
cc Nancy_O'Malley@albemarle.com

Subject HPV Update CAS 1709-70-2

<<HPV Cover letter November 2006 IRGANOX 1330 - ETHANOX 330 .pdf>> <<HPV Test Plan for Irganox 1330 - Ethanox 330 revised Nov 2006_.pdf>> <<Robust Summaries for Irganox 1330 - Ethanox 330 Nov 2006 .pdf>>

To: EPA HPV Program Administrators

Attached is a revised test plan and robust summaries for CAS 1709-70-2 (Irganox 1330 / Ethanox 330).

Please let me know if you have questions or need additional information.

We believe our submission is now final for this compound.

Sincerely yours,

Richard Balcomb



Ciba Specialty Chemicals HPV Cover letter November 2006 IRGANOX 1330 - ETHANOX 330 .pdf



HPV Test Plan for Irganox 1330 - Ethanox 330 revised Nov 2006_.pdf



Robust Summaries for Irganox 1330 - Ethanox 330 Nov 2006 .pdf

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Ciba Specialty Chemicals
CorporationRichard Balcomb
Head, Toxicology and
Environmental AssessmentsExpert Services
540 White Plains Road
Tarrytown, New York USA 10591
Ciba

November 14, 2006

Stephen L. Johnson
Administrator
US Environmental Protection Agency
HPV Challenge

Subject: Revised Test Plan and Robust Summaries for IRGANOX 1330 / ETHANOX[®] 330
1,3,5-trimethyl-2, 4,6-tris (3,5-di-t-butyl-4-hydroxybenzyl) benzene
CAS No. 1709-70-2

Dear Mr. Johnson:

Ciba Specialty Chemicals Corporation and Albemarle Corporation support EPA's High Production Volume (HPV) chemical challenge program and its effort to gather and publish basic hazard information on those chemicals manufactured at high volumes in the United States. Ciba Specialty Chemicals Corporation and Albemarle Corporation are co-sponsors for 1,3,5-trimethyl-2, 4,6-tris (3,5-di-t-butyl-4-hydroxybenzyl) benzene. Enclosed are a revised test plan and robust summaries for IRGANOX 1330 / ETHANOX[®] 330. The revisions address EPA's comments published October 20, 2005.

EPA's comments on the Environmental Fate robust summaries are straightforward, as are the revised summaries submitted here, and no additional discussion is needed.

EPA's comments on the Health Effects data are more complex and therefore deserve comment. First, EPA indicated that the repeat-dose testing originally submitted described exposures below the recommended limit dose and that the sponsors should prepare a robust summary based on published testing at higher concentrations (Stevenson et al. 1965). We have followed this recommendation and a new robust summary is included addressing this work.

The agency also commented that a chromosome aberration test was needed despite the availability of long-term carcinogenicity studies and reproduction studies for the compound. We strongly believe that conducting this study would not further our knowledge on this chemical. Moreover, Irganox 1330 / Ethanox 330 is structurally related to several hindered phenol antioxidants also involved in the HPV program,

notably CAS 6683-19-8, CAS 27676-62-6 and CAS 2082-79-3¹ and these data support a very low concern for clastogenic effects and indicate that a chromosome aberration study is not needed to assess risk.

Sincerely yours,

Richard Balcomb

Cc: Dr. Nancy O'Malley, Albemarle Corporation

¹ For additional supporting data relating to hindered phenol antioxidants, information presented for the HPV Hindered Phenol Category, sponsored by the American Chemistry Council, should also be reviewed.